

## Remarks/Arguments:

**Rejections under 35 U.S.C. 112**

The Examiner has rejected claims 27-30 under 35 U.S.C. 112 second paragraph as indefinite. The Examiner states more specifically that the limitation “particle-filled bladder” is not described in the specification in such a way as to enable one of skill in the art to make the invention because the spec contains insufficient disclosure with respect to the type, hardness or size of particles. Applicant respectfully submits that the function of the particles is not so dependent on size, type or hardness that one of skill in the art would not be able to choose functional sizes, hardnesses or types without undue experimentation. Note that the Applicant states, in [0064], that the bladder “takes a set, which can be reconfigured again and again over the face of the patient.” One of skill in the art would thus realize that the particles should have sizes on a scale much smaller than the scale of the bladder; that the particles be relatively inert with respect to each other and with respect to the fluid (if present at all) in the bladder such that cohesiveness or other interactions do not interrupt the ability of the particles to take on a new set; etc.

The examiner further rejects claims 27-30 under 35 U.S.C. 112 second paragraph because from the description given, one cannot determine the metes and bounds of the invention. Applicant respectfully submits that for the reasons given in the prior paragraph, one of skill in the art would be able to easily determine, without undue experimentation, the parameters of particles which could successfully be used in the masks of the present invention.

**Rejections under 35 U.S.C. 103****Matula, Jr. et al**

Claim 27 has been rejected under U.S.C. 103 (a) as being unpatentable over Matula Jr. et al. US 2006/0231103. The Examiner has argued that Matula discloses, in Figure 11, a face-seal liner comprising an elastomeric bladder filled with particles. Applicant respectfully submits that the “foam or other particulate matter” mentioned in the referenced paragraph [0087] refers to a material which is not particulate in the sense of the word understood by one of skill in the art. In fact, the paragraph is certainly referring, not to particles, but to porous

materials, such as sintered materials, which are made from particles. Applicant points out that only this interpretation is feasible because, in the embodiment at issue, the bladder is filled with a gas which is pumped into the bladder through a channel which is, as depicted in Figure 11, of a size on the order of the size of the bladder. An open channel is incompatible with the interpretation of particulate understood by one of skill in the art (powder) because it would lead to loss of the particulate into the cavity between the mask and the wearer.

Furthermore, the paragraph refers to “foam and other particulate,” indicating that foam and “other particulate” are alike in structure (i.e., not similar to the “skilled in the art” interpretation of “particulate” as a powder). Applicant suggests that the real interpretation of the phrase “other particulate” is directed toward materials *prepared* from particles, such as sintered or compressed materials, as such materials are compatible with the function of the ‘103 device. Applicant respectfully requests that the rejection be withdrawn.

Barnett et al

The Examiner has rejected Claims 27-30 as being unpatentable over Barnett et al., U.S. application publication No. US 2006/0076018. The Examiner argues that the reference discloses a face-seal interface for a respiratory mask comprising an elastomeric bladder [0051]. The Examiner further argues that while the reference fails to disclose the “particle-filled” limitation, it would be obvious to fill the elastomeric bladder with particles because “particulate fillers are well-known modifiers.”

Applicant respectfully disagrees, and draw the Examiner’s attention to paragraphs [0022]-[0025] which summarize the essence of the invention in the ‘018 application. The seal disclosed therein comprises two components. One component is intended to permanently adapt to the macrocontours of a wearer’s face (a “selectively formable substance that is adapted to being molded from a first pattern into a second pattern and retain the second pattern..” paragraph [0022]). The other component is intended to *reversibly* adapt to the microcontours (soft tissue) of the wearer’s face (a pliable gel substance that recoils back to substantially its original shape when not stressed...” paragraph [0022]). The reversibility is thus essential to the face-seal contact formed by the seal of the ‘018 application. Applicant respectfully points out that the type of interface between the seal of the ‘018 application and the face of the wearer is due to the reversible deformation of the seal upon being situated upon the wearer. The essential difference between the ‘018 seal and Applicant’s seal is that

the '018 seal surface retains a bias against the skin of the wearer. Applicant's seal, on the other hand, comprises particles (and, optionally, a fluid plasticizer). Upon contacting the face of the wearer, the particles shift in such a way to relieve bias, and upon the shift, the final particle configuration is *not* characterized by bias against the skin of the wearer due to particles seeking to return to a prior configuration. Again, with respect to the functioning of '018 seal, a retained bias is critical. Applicant thus respectfully suggests that one of skill in the art who has read the '018 disclosure would not be motivated to substitute a particulate, with or without the fluid plasticizer, for the two component gel seal of the '018 application, because it would be contrary to the teachings of the reference. Applicants respectfully request that the rejection be withdrawn.

Chen

Claims 27, 29 and 30 are rejected under 35 U.S.C. 103 (a) as being unpatentable over US Application Publication No. 2003/0122446 to Chen.

The Examiner asserts that paragraph [0237] suggests a bladder filled with particles. Applicant respectfully points out that the paragraph teaches composite articles, comprised of one or more gels and one or more substrate materials, in which the gels are "interlocked" with the substrate materials. A gel bladder filled with particles does not constitute a composite article in which a substrate and gel are interlocked. With respect to the former, substrate and gel are immobilized with respect to each other, while a gel bladder filled with particles allows for shifting of the particles with respect to the gel, enabling the bladder to adopt a range of shapes in response to wearer facial contours.

The Examiner suggests that the Figures illustrate a filled gel. However, referring to [0005], to the Applicant's best discernment, the Figures illustrate gel products in which the core is a gel, not a particulate.

The Examiner asserts that the incorporation, into a gel, of particles reading on the claims is disclosed in [0231]. Applicant respectfully submits that the paragraph refers to additives which can be incorporated into a gel, and one of skill in the art would recognize that the word "additive" specifies the spatial relationship between the gel and the additive substance. Irrespective of what is done with the gel, whether it is stretched into sheets or formed into three dimensional objects, the additive is within the confines of the gel itself.

Thus, a bladder formed from a gel and having a void filled with a substance is distinct from a gel which contains the substance as an additive.

The Examiner asserts that the use of silicon oil to fill a bladder is disclosed in paragraphs [0204] – [0212]. However, the referenced section discusses the use of silicon oil to extract other oils from gels which are pregnated with oil. See in particular [0206] in which it is clear that silicon oils aid in the extraction of other oils contained in the gel. The section fails to teach even a gel bladder, let alone a gel bladder having a reservoir of silicone oil within, let alone a bladder filled with particles, the interstitial spaces filled with a silicone oil.